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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,862

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Suresh Pareek

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,862	<b>Applicant(s)</b> PAREEK ET AL.	
	<b>Examiner</b> S. TRAN	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

Claims 1-8, 11-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. US 2004/0028737, in view of Mehra et al. US 5,733,575.

Deshpande teaches an enteric coating composition comprising methacrylate copolymer type C, polyethylene glycol 600, titanium dioxide, and talc (examples 1-4 and 8). The amounts of the above components disclosed in the examples fall within the claimed ranges, e.g., about 60% methacrylate copolymer type C, about 6% plasticizer, about 7% opacifier, and about 24% detackifier.

Deshpande does not expressly teach that the coating composition is in powder form.

Mehra teaches a powder coating composition that is non-toxic and edible. The powder coating composition comprising enteric film forming polymer (abstract; and columns 3-4). Thus, it would have been obvious to one of ordinary skill in the art to prepare a coating composition in powder form in view of the teachings of Mehra to obtain the claimed invention. This is because Mehra teaches a dry powder coating that can overcome the disadvantages of the known aqueous coating compositions (column 1), because Mehra teaches a dry powder coating composition that is non-toxic and edible, because Mehra teaches that a dry powder coating composition provides an enteric coating that is less tacky and does not have the odor of ammonium hydroxide, and because Mehra teaches that a dry powder coating composition is known in the art.

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Claims 9, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. US 2004/0028737, in view of Mehra et al. and Kokubo et al. US 4,948,622.

Deshpande is relied upon for the reason stated above. Deshpande does not expressly teach the use of pigment in the coating composition.

Kokubo teaches a coating composition comprising edible dyes, and edible lake pigments (column 3, lines 45-50). Thus, it would have been obvious to one of ordinary skill in the art to modify the coating composition of Deshpande to include the use of edible pigments in view of the teachings of Kokubo to obtain the claimed invention. This is because Kokubo teaches that the presence of pigment in a coating composition is well known in the art.

### ***Response to Arguments***

Applicant's arguments filed 04/06/10 have been fully considered but they are not persuasive.

Applicant argues that if the outer layer of Deshpande alone were considered as the enteric film coating composition, the reference fails to disclose the concentration of methacrylate copolymer of Type C of about 20-90 wt% in the outer layer, and none of the outer layer compositions in examples of the reference includes the particular composition including the plasticizer, a film coating detackifier, and an opacifier in addition to about 20-90 wt% methacrylate copolymer of Type C and excluding the alkalinizing agent as claim 1 recites (see examples 1-4 on pages 3-4 of the reference).

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Deshpande does not teach or suggest that the inner layer alone is an enteric coating (see para. [0040]).

However, in response to Applicant's arguments that *the reference fails to disclose the concentration of methacrylate copolymer of Type C of about 20-90 wt% in the outer layer, and none of the outer layer compositions in examples of the reference includes the particular composition including the plasticizer, a film coating detackifier, and an opacifier in addition to about 20-90 wt% methacrylate copolymer of Type C and excluding the alkalinizing agent as claim 1 recites*, the Examiner notes that: 1) the claims do not require that components a) through d) present altogether. Claim 1 recited that the coating composition comprising a, b, c, d in the absent of and/or. Accordingly, the claims are interpreted in an alternative manner; 2) all of the examples in Deshpande disclosed at least 59% of methacrylate copolymer of Type C; and 3) the examples also disclosed the present of plasticizer such as PEG 600.

In addition, Applicant argues that even if the combination of the outer and inner layers of Deshpande were considered as the enteric coating, which Applicants do not concede, Deshpande includes 2M ammonia solution in suspension of the inner layer composition, i.e., the alkalinizing agent, which claim 1 excludes from the composition, in order to adjust pH to neutral or nearly neutral (see *id.*). Although the alkalinizing agent such as 2M ammonia solution is added to a suspension in a liquid form, the alkalinizing agent is an essential element for the inner layer composition of Deshpande to obtain the neutral or near neutral pH and protect the acid unstable active ingredient from the outer

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acidic pH layer as discussed above (see para. [0038] on page 2 and para. [0040] on page 3). The composition does not include the essential element, and thus there is no reasonable basis to assume that the composition excluding the essential element, i.e., alkalinizing agent, would exhibit the same properties as those of the composition including the essential element. By having one composition for enteric film coating excluding the alkalinizing agent as claim 1 recites, the composition is readily dispersible in water without caking or agglomeration, and the coating film has good tensile strength, has good stability, and is tack free (see "Summary of the invention" on pages 2-3 of the specification). Such properties obtained with one enteric coating composition excluding the alkalinizing agent, which is commonly used to increase stability of the coating (see last para. on page 2 of the specification), are unexpected from Deshpande. Also, it is clearly advantageous for a pharmaceutical formulation to have one coating layer, which requires a fewer steps than the formulation having two coating layers, particularly in commercial production.

However, in response to Applicant's arguments, the Examiner notes that the limitation "alkalizing agent" has not been defined to include ammonia solution. In the present case, Deshpande teaches the use of 2M ammonia solution as a pH adjusting agent.

Further in response to Applicant's arguments with respect to Mehra and Kokubo, it is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the

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references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Kokubo is cited solely for the teaching of the use of pigment in the coating composition is known in the art. Further, as discussed above, the claims do not require the present of all components. Mehra is cited solely for the teachings of powder coating composition.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/  
Primary Examiner, Art Unit 1615